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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/660,301

09/10/2003

Brett P. Giroir

UTSD:1477

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07/14/2006

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EXAMINER

CROWDER, CHUN

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/660,301

Applicant(s)

GIROIR ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/23/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Examiner of this application in the PTO has changed. TO aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Chun Crowder, Group Art Unit 1644, Technology Center 1600.

2. Applicant's amendment, filed 04/23/2006, is acknowledged.

Claims 1-3, 7, 8, 11, 12, 15, and 16 have been amended.

Claims 1-19 are pending and currently under consideration.

3. The text of those sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

This Office Action will be in response to applicant's amendment, filed 04/23/2006.

The rejections of record can be found in the previous Office Action, mailed 04/17/2006.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The terms "a test MIF concentration" and "a control MIF concentration" in claims 1-19 and the phrase "not associated with cardiovascular risk indicates that the person is subject to elevated cardiovascular risk" as recited in claims 1-6 are not supported by the original disclosure or claim as filed.

Applicant's amendment, filed 04/23/06, asserts that no new matter has been added. However, applicant has not pointed out the support for the limitations of "a test MIF concentration", "a control MIF concentration", and "not associated with cardiovascular risk indicates that the person is subject to elevated cardiovascular risk" in the instant specification.

However, the specification as filed does not provide sufficient written description of the above-mentioned "limitations". The specification does not provide sufficient support for "a test MIF concentration", "a control MIF concentration", and "not associated with cardiovascular risk indicates that the person is subject to elevated cardiovascular risk".

The specification only discloses obtaining a level of MIF in the individual and comparing the level of the marker to a predetermined value; the instant claims now recite "a test MIF concentration", "a control MIF concentration", and "not associated with cardiovascular risk indicates that the person is subject to elevated cardiovascular risk". Therefore, the claims represent a departure from the specification and claims originally filed. Applicant's reliance on generic disclosure of MIF concentration and predetermined value do not provide sufficient direction and guidance to the features currently claimed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679 683 (CCPA 1972) and MPEP 2163.05.

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

5. Claim 1 stand rejected under **35 U.S.C. 102(b)** because claim 1 is anticipated by Yabunaka et al. (Diabetes Care. 2000. 23;2:256-258) for reasons of record set forth in the previous Office Action, mailed 04/17/2006.

Applicant asserts that the amended claim 2 has been restricted to the subject matter of non-rejected claims.

This is not found persuasive because Yabunaka et al. compare the concentration of serum MIF in type 2 diabetic patients to those normal healthy control subjects and teach that the serum level of MIF in type 2 diabetic patients is significantly high compared with that in normal control subjects. It is noted that type 2 diabetic patients fit the criteria of a person not predetermined to be subject to cardiovascular disease.

It is further noted that "consist of" (line 7 of claim 1) in the body of claim 1 does not limit the open-ended "comprises" (line 7 of claim 1) language in the claims.

Therefore, the prior art teachings anticipate one of the elements of Markush claim in claim 1 (e.g. (a)).

6. Upon further consideration, as well as applicant's amendment, the previous rejection under 35 U.S.C. 112, second paragraph has been withdrawn.

7. ***Conclusion: no claim is allowed.***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.


Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.

Patent Examiner

June 27, 2006


PHILLIP GAMBEL, PH.D., J.D.
PRIMARY EXAMINER
TR 1600
7/3/06